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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,669	08/27/2001	Jens Petersen	60117.000004	2508

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EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/06/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,669

Applicant(s)

Petersen

Examiner

Carlos Azpuru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 3, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) 1-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) is/are allowed.
- 6) ☒ Claim(s) 27-31 is/are rejected.
- 7) ☐ Claim(s) is/are objected to.
- 8) ☐ Claims are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

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DETAILED ACTION

Receipt is acknowledged of the extension of time and response filed 03/03/03.

An election was made on 03/27/03.

Election/Restrictions

Applicant's election with traverse of Group IV, claims 27-31 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the hydrogel as defined is novel and so are the methods of using it. This is not found persuasive because a search of all four groups would entail an undue burden on this office.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-26 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claim 31, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

See MPEP § 2173.05(d).

Double Patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18 and 19 of copending Application No. 09/938,667 ('667). Although the conflicting claims are not identical, they are not patentably distinct from each other because '667 claims a prosthetic device which is injectable, and comprises a hydrogel which is made by reacting acrylamide, and methylene bis-acrylamide using a radical initiator. The result is a polyacrylamide gel. The amount of polyacrylamide gel can be less than 3.5% by weight, and should also contain at least 75% pyrogen-free water or saline solution. The prosthetic may also contain stem cells. The claims of '667 differ only in that the intended use of the prosthetic in that case is for prevention of incontinence and vesicoureteral reflux. This is an intended use however, and does not lend a patentable distinction. Further, the instant claims are generic to soft tissue augmentation. It would have therefore been well within the skill of the ordinary practitioner to claim the instant claims given the claims of '667, with the expectation of providing reasonable soft tissue

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augmentation as provided in the urethra , colon or rectum in claims of '667. There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the instant claims would have been obvious give the claims of '667.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 27-31 are 09/938,670 ('670) provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. '670. Although the conflicting claims are not identical, they are not patentably distinct from each other because '670 claims an endoprosthesis which is injectable, and comprises a hydrogel which is made by reacting acrylamide, and methylene bis-acrylamide using a radical initiator. The result is a polyacrylamide gel. The amount of polyacrylamide gel can be less than 3.5% by weight, and should also contain at least 95% pyrogen-free water or saline solution The prosthetic may also contain stem cells. It would have therefore been well within the skill of the ordinary practitioner to claim the instant claims given the claims of '670, with the expectation of providing reasonable soft tissue augmentation as provided in the claims of '670. There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the instant claims would have been obvious give the claims of '670.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 27-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-35 of copending Application No. 09/938,668 ('668). Although the conflicting claims are not identical, they are not patentably distinct from each other because '668 claims a prosthetic device which is injectable, and comprises a hydrogel which is made by reacting acrylamide, and methylene bis-acrylamide using a radical initiator. The result is a polyacrylamide gel. The amount of polyacrylamide gel can be less than 3.5% by weight, and should also contain at least 75% pyrogen-free water or saline solution. The prosthetic may also contain stem cells. The claims of '668 differ only in that the intended use of the prosthetic in that case is for augmenting or replacing cartilage in the intra-articular cavity.. This is an intended use however, and does not lend a patentable distinction. Further, the instant claims are generic to soft tissue augmentation. It would have therefore been well within the skill of the ordinary practitioner to claim the instant claims given the claims of '667, with the expectation of providing reasonable soft tissue augmentation as provided for the cartilaginous tissues of '668. There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the instant claims would have been obvious given the claims of '668.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunstedt et al (reference F2 on IDS).

Brunstedt et al disclose a soft tissue prosthesis which may be composed of various polymers including polyacrylamide (see claim 1). The polymerization of methylene bis-acrylamide and acrylamide is disclosed at col. 10, lines 25-40. At col. 4, lines 33-34, the percent composition may be between 2 to 20%. The reference differs only in the disclosure of various other polymers which may also function for their art recognized use as soft tissue prostheses. However, the selection of polyacrylamide from among the list of disclosed gels would have been well within the skill of the ordinary practitioner given the disclosure of Brunstedt et al. Further, those of ordinary

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skill would have expected similar soft tissue augmentation given the disclosure of Brunstedt et al which clearly defines the therapeutic use of the prosthesis for soft tissue. Therefore, the instant prosthetic devise would have been obvious given the disclosure of Brunstedt et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca
May 4, 2003


CARLOS AZPURU
PRIMARY EXAMINER
GROUP 1500